Remarks

Claims 1-6, 8, 9-18, 20, 22, 24, 26-28, 34-37, 60, 67-68 and 70 remain pending in the application. Claims 1, 9, 10, 24, 26 and 60 have been amended herein. Claims 7, 19, 21, 23, 25, 29-33, 38-59, 61-66, 69, and 71-102 have been canceled. No new matter has been added by this amendment.

For the purpose of clarifying issues on appeal, all claims have been amended to include a specific concentration range of the surfactant SDS as provided in rejected claim 53, i.e., SDS within the range of 0.003% to 0.01%. Amendments presenting rejected claims in better form for consideration on appeal may be admitted after a final rejection. 37 C.F.R. §1.116 (b).

Claim Rejections – 35 U.S.C. § 112

Claims 1 – 102 were rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The use of the term "ionophoric" was at issue. Amendments have been made to remove this term. It is Applicant's contention that one of ordinary skill in the art would appreciate that at the time the application was filed Applicant had possession of the claimed invention, i.e., one of ordinary skill in the art would recognize that the surfactants utilized could be characterized as having ionophoric properties. *See*, Mohan, Lawrence, Dow.

Claim Rejections – 35 U.S.C. § 112

Claims 1-102 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Pending claims have been amended herein and as a result, reconsideration of the rejection is requested.

Claim Rejections – 35 U.S.C. § 102(b) – Lai et al

Claim 1, 3, 8-12, 15, 17, 18, 20 22, 24, 26-38, 42, 44, 49-53, 60, 61, 65-69, 71, 81-84, 86, 87, 90, 92, 93, 95, 96 and 100 were rejected under 35 U.S.C. §102(b) as being anticipated by Lai et al.

All independent claims have been amended to include the limitations of claim 53, i.e. SDS use in the specific concentration range of 0.003% to 0.01%.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P. §2131.

Lai et al. discloses a solution of 30:70 THF:SDS, 0.07M SDS. An SDS concentration of 0.07M equates to approximately 2.02%. Unlike the present invention, Lai et al. teaches surfactant concentration ranges of SDS at micellar concentrations. Micelles are colloidal particles consisting of many molecules. Stedmans Medical Dictionary. Solutions of surfactants above a critical micellar concentration (CMC) are often used to facilitate solubility of compounds, the micellar complexes of ion surfactants allowing incorporation of water insoluble substrates in the hydrophobic part. Bagno, p. 1079. The concentration of SDS of Lai et al. would not promote ionophoric behavior as the surfactant concentrations are above the respective critical micelle concentrations (CMC for SDS is approximately 0.23%). *See*, Reddi et al., Critical Micelle Concentrations of Aqueous Surfactant Systems, NSRDS-NBS 36. Calculations reveal that the concentration of SDS in Lai et al. is approximately 10 times greater than the critical micelle concentration (and at least approximately 25 times greater than the highest concentration of SDS of the present claims).

The claims as amended are directed to specific non-micelle forming concentration ranges of SDS. The use of SDS at the micellar concentrations of Lai and Reddi is to facilitate solubility of porphyrin through micelle formation. Reddi, p. 642 – 643. SDS in Lai et al. is provided at concentrations at which the surfactant does not function as ionophores. Williams et al also teaches the use of surfactants at micellar concentrations to facilitate solubility of compounds.

A proposed modification of Lai et al. to lower the concentrations of SDS to the presently claimed ranges would not be obvious as such a modification would render the prior art invention

unsatisfactory for its intended purpose, i.e. to improve the solubility of poorly soluble porphyrin (surfactant concentrations above CMC are necessary to form micellar complexes and improve solubility). *See*, M.P.E.P §2143.01, citing In re Gordon, 733 F2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Furthermore, any proposed modification of Lai et al to lower the concentration of SDS to the presently claimed ranges would not be obvious as such a modification would change the principle of operation of the prior art invention being modified. *See*, M.P.E.P §2143.01, citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The presently claimed concentration range of SDS would not be an obvious variation of the teachings of Lai et al., as such modifications would render the prior art invention unsatisfactory for its intended purpose, i.e., to improve the solubility of poorly soluble porphryn. Further, any proposed modification of Lai et al. to lower the concentration of SDS to the presently claimed ranges would not be obvious as such modification would change the principle of operation of the prior art invention being modified.

No combination of the references would teach or suggest the claim limitation of a specific concentration range of SDS. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Claim Rejections – 35 U.S.C. § 102(b) – Nitzan

Claim 1-3, 6, 8, 10-12, 15, 18, 26, 30, 32, 37, 39, 44, 45, 48, 49, 51, 52, 80-83, 85-89, 92, 95, 97 and 101 were rejected under 35 U.S.C. §102(b) as being anticipated by Nitzan. All independent claims have been amended to include the limitations of claim 53. For the reasons set forth above, reconsideration of the rejection of these claims is solicited.

Claim Rejection: 35 U.S.C. §103 –Swartz Nitzan Williams

Claims 1, 4, 5, 10, 13, 14, 17, 23, 26-28, 34, 36, 40, 41, 43, 46, 47, 54-57, 59-64, 72-76, 78 and 79 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz in combination with Nitzan et al and Williams et al.

All independent claims have been amended to include the limitations of claim 53. For the reasons set forth above, reconsideration of the rejection of these claims is solicited.

Claim Rejection: 35 U.S.C. §103 Swartz Nitzan Williams

Claims 9, 19-22, 95, 98 and 99 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz in combination with Nitzan et al and Williams et al.

All independent claims have been amended to include the limitations of claim 53. For the reasons set forth above, reconsideration of the rejection of these claims is solicited.

Claim Rejection: 35 U.S.C. §103 Wilk Nitzan

Claim 16 was rejected under 35 U.S.C. §103(a) as being unpatentable over Wilk et al in combination with Nitzan et al.

All independent claims have been amended to include the limitations of claim 53. For the reasons set forth above, reconsideration of the rejection of these claims is solicited.

Claim Rejection: 35 U.S.C. §103 Lai et al Nitzan et al

Claims 10, 25, 60, 70, 87, and 91 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lai et al in combination with Nitzan et al.

All independent claims have been amended to include the limitations of claim 53. For the reasons set forth above, reconsideration of the rejection of these claims is solicited.

Claim Rejection: 35 U.S.C. §103 –Swartz Nitzan Williams

Claims 58 and 77 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz et al in combination with Nitzan and Williams, and further in view of Singer et al.

Claims 58 and 77 have been canceled.

Claim Rejection: Double Patenting

Claims 1-102 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,251,127 in view of Rothstein. It is respectfully submitted that the claims as now amended define an invention which is not merely an obvious variation of an invention claimed in U.S. Patent No. 6,251,127. Neither reference teaches or suggests the use of SDS at the concentration range as presently claimed.

Applicant respectfully requests that the Examiner enter the above amendments to place the rejected claims in better form for consideration on appeal.

Please direct any questions regarding this application to John Klos at (612) 321-2806.

Respectfully submitted,
Merrill A. Biel, and Advanced Photodynamic Technologies, Inc. by their attorneys

Dated: January 15, 2003

By: John Klos

John F. Klos, Esq.
Registration No. 37,162
Fulbright & Jaworski L.L.P.
225 South Sixth Street, #4850
Minneapolis, MN 55402-4320
Telephone: (612) 321-2806

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8: I hereby certify that this paper and any papers referred to herein are being deposited with the U.S. Postal service, as first class mail, postage prepaid, addressed to Commissioner for Patents, Washington, D.C. 20231 on January 15, 2003. John F. Klos: John Klos

(Marked-Up Version Showing Application as Amended 1/15/2003)

In the Claims:

1. (twice amended) A method of photoeradication of cells comprising the steps of:

identifying an area of cell activity;

applying a concentration including a combination of a surfactant and a photosensitizing agent to the area of cell activity, said surfactant being a solution of SDS with a concentration range of 0.003% to 0.01%, said surfactant [having ionophoric properties and] producing a disorientation of a cell membrane so that said cell membrane no longer functions as an effective osmotic barrier, thereby allowing the photosensitizing agent to pass through the cell membrane and into the cell interior; and

exposing the area of cell activity to a light having a light wavelength, light dosage and a light dosage rate, thereby activating the photosensitizing agent within the cell interior to cause internal photodynamic cell destruction.

Cancel claim 7

9. (twice amended) A photodynamic therapy treatment kit comprising:

a volume of a concentration including a combination of a surfactant [having ionophoric properties]and a photosensitizing agent, said surfactant being a solution of SDS with a concentration range of 0.003% to 0.01%, said surfactant producing a disorientation of a cell membrane so that said cell membrane no longer functions as an effective osmotic barrier, thereby permitting the photosensitizing agent to pass into the cell interior and

a light emitting treatment device configured to emit light and to activate photosensitizing agent within the cell interior to cause internal photodynamic destruction of the cell.

10. (twice amended) A method of treatment comprising:

selecting one or more cells;

disposing a concentration in proximity to the one or more cells, said concentration including a combination of a surfactant [having ionophoric properties] and a photosensitizing agent on the one or more cells, said surfactant being a solution of SDS with a concentration range of 0.001 to 0.01%, said surfactant disorienting a cell membrane so that said cell membrane no longer functions as an effective osmotic barrier, thereby permitting the photosensitizing agent to pass into the one or more cells; and

applying a light in proximity to the one or more cells, wherein the combination of the light and photosensitizing agent within the one or more cells causes internal photodynamic disruption of the one or more cells.

Cancel claims 19, 21 and 23

24. (twice amended) The method of treatment according to claim 10 wherein the combination includes [a surfactant having ionophoric properties and] more than one photosensitizing agent.

Cancel claim 25

26. (twice amended) A method of cell disruption comprising:

selecting one or more cells;

disposing a photosensitizing agent in proximity to the one or more cells;

disposing a surface acting agent in proximity to the one or more cells, said surface acting agent being a solution of SDS with a concentration range of 0.003% to 0.01%, said surface acting agent [having ionophoric properties and] disorienting a cell membrane so

that said cell membrane no longer functions as an effective osmotic barrier, whereby the photosensitizing agent passes through the cell membrane; and

applying a light in proximity to the one or more cells to cause internal photodynamic cellular disruption of the one or more cells.

Cancel claims 29 - 33

Cancel claims 38- 59

60. (twice amended) A treatment protocol for a living body having cancer cells, said protocol comprising the steps of:

identifying cancer cells within the living body;

selecting a chemical agent [having ionophoric properties] to disrupt a membrane of the cancer cells, said chemical agent being a solution of SDS with a concentration range of 0.003% to 0.01%, ;

administering the chemical agent to the living body, said chemical agent disorienting a cancer cell membrane so that said membrane no longer functions as an effective osmotic barrier;

administering a photosensitizing agent to the living body, said photosensitizing agent passing through the cancer cell membrane; and

applying a light in proximity to the cancer cells, the combination of photosensitizing agent within the cell interior and light resulting in internal photodynamic disruption of the cancer cells.

Cancel claims 61 –66, 69 and 71-102